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Dated: 5-10-05 Signature: [Signature]
Printed Name: C. A. BRADLEY

Docket No.: 60710-00002USC1
(PATENT)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Charles F. Brunicardi

Application No.: 10/656450

Confirmation No.: 8472

Filed: September 5, 2003

Art Unit: 1632

For: PROMOTER DRIVEN TISSUE SPECIFIC
CYTOTOXIC AGENTS AND METHODS OF
USE

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached substitute for form 1449A/B/PTO. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

The attached substitute lists the same references as were provided with an Information Disclosure Statement (IDS) for a related family member -- continuation application 10/948,872. Also, all references except thirteen references (i.e., CZ1, CA2, CB2, CB2, CC2, CD2, CE2, CF2, CG2, CH2, CA3, CB3 and CC3) were listed with an IDS, or cited by the Examiner, in the prosecution of parent application 09/686,631 (now U.S. Patent No. 6,716,824). Of the remaining thirteen references, the first ten references (i.e., CZ1, CA2, CB2, CB2, CC2, CD2, CE2, CF2, CG2, CH2) were previously provided in an IDS submitted December 14, 2003 for this application. The remaining three references (i.e., CA3, CB3 and CC3, which are provided with this IDS) are:

CA3	WANG et al., "Specific Gene Expression and Therapy for Pancreatic Cancer Using the Cytosine Deaminase Gene Directed by the Rat Insulin Promoter", J of GASTROINTESTINAL SURGERY, 2004, Vol. 8 No. 1: 98-108.
CB3	TIRONE et al., "Insulinoma-Induced Hypoglycemic Death in Mice is Prevented with Beta Cell-Specific Gene Therapy", ANNALS OF SURGERY, May 2001, Vol. 233, No. 5: 603-611
CC3	TIRONE et al., "Cell-specific Cytotoxicity of Human Pancreatic Adenocarcinoma Cells Using Rat Insulin Promoter Thymidine Kinase-directed Gene Therapy", WORLD J. OF SURGERY, 2004, 28: 826-833.

This IDS is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

In accordance with 37 CFR 1.97(g), the filing of this IDS shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this IDS shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the IDS is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

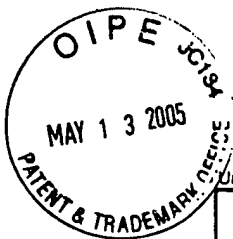
The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 10-0447, under Order No. 60710-00002USC1.

Dated: *May 9, 2005*

Respectfully submitted,

By *Mark J. Gatschet*
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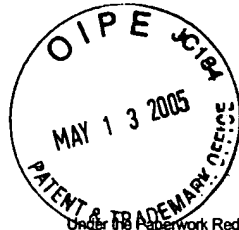


TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/656450-Conf. #8472
	Filing Date	September 5, 2003
	First Named Inventor	Charles F. Brunicardi
	Art Unit	1632
	Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission	Attorney Docket Number	60710-00002USC1

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Return Receipt Postcard Certificate of Mailing Substitute for form 1449A/B/PTO Non-Patent References (Wang et al., 2004; Tirone et al., 2001; and Tirone et al., 2004)
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Sheet	1	of	4	Attorney Docket Number	60710-00002USC1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA**	US-5,997,859-A1	12-07-1999	Barber et al.	
	AB**	US-6,066,624-A1	05-23-2000	Woo et al.	
	AC**	US-6,241,982B1-A1	06-05-2001	Barber et al.	
	AD**	US-6,217,860B1-A1	04-17-2001	Woo et al.	
	AE**	US-5,674,703-A1	10-07-1997	Woo et al.	
	AF**	US-5,631,236-A1	05-20-1997	Woo et al.	
	AG**	US-5,811,266-A1	09-22-1998	Newgard	
	AH**	US-5,952,221-A1	09-14-1999	Kurtzman et al.	
	AI**	US-5,723,333-A1	03-03-1998	Levine et al.	
	AJ**	US-5,885,971-A1	03-23-1999	German et al.	
	AK**	US-5,880,261-A1	03-09-1999	Waeber et al.	
	AL**	US-5,863,794-A1	01-26-1999	Strayer	
	AM*	US-5,837,693-A1	11-17-1998	German et al.	
	AN**	US-5,837,283-A1	11-17-1998	McDonald et al.	
	AO**	US-5,792,656-A1	08-11-1998	Newgard	
	AP**	US-5,747,325-A1	05-05-1998	Newgard	
	AQ**	US-5,858,973-A1	01-12-1999	Habener et al.	
	AR**	US-5,728,379-A1	03-17-1998	Martuza et al.	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)			
	BA**	WO-WO 95/05835-A1	03-02-1995		

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CA**	DIMAIO et al., "Directed enzyme pro-drug gene therapy for pancreatic cancer <i>in vivo</i> ", SURGERY, Vol. 116, No. 2, 1994, pp. 205-213.	
	CB**	EASTHAM et al., "Prostate Cancer Gene Therapy: Herpes Simplex Virus Thymidine Kinase Gene Transduction Followed by Ganciclovir in Mouse and Human Prostate Cancer Models", HUMAN GENE THERAPY, 1996, 7:515-523.	
	CC**	FRAZIER, "Gene Expression in Pancreatic Adenocarcinoma", ANNALS NEW YORK ACADEMY OF SCIENCES, 1999, 880:1-4.	
	CD**	HAMAGUCHI et al., "NIT-1, A Pancreatic β -Cell Line Established from a Transgenic NOD/Lt Mouse", DIABETES, 1991, 40:842-849.	
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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/656450
				Filing Date	September 5, 2003
				First Named Inventor	Charles F. Brunicardi
				Art Unit	1632
				Examiner Name	Not Yet Assigned
Sheet	2	of	4	Attorney Docket Number	60710-00002USC1

	CE**	HARDY et al., "Construction of Adenovirus Vectors through Cre-Lox Recombination", JOURNAL OF VIROLOGY, Vol. 71, No. 3, 1997, pp. 1842-1849.	
	CF**	KATABI et al., "Hexokinase Type II: A Novel Tumor-Specific Promoter for Gene-Targeted Therapy Differentially Expressed and Regulated in Human Cancer Cells", HUMAN GENE THERAPY, 1999, 10:155-164.	
	CG**	KANEKO et al., "Adenovirus-mediated Gene Therapy of Hepatocellular Carcinoma Using Cancer-specific Gene Expression", CANCER RESEARCH, 1995, 55:5283-5287.	
	CH**	KIJIMA et al., "Application of the Cre Recombinase/loxP System Further Enhances Antitumor Effects in Cell Type-specific Gene Therapy against Carcinoembryonic Antigene-producing Cancer", CANCER RESEARCH, 1999, 59:4906-4911.	
	CI**	KUMAR et al., "Subtype-Selective Expression of the Five Somatostatin Receptors (hSSTR1-5) in Human Pancreatic Islet Cells: A Quantitative Double-Label Immunohistochemical Analysis", DIABETES 1999, 48:77-85.	
	CJ**	LIEBER et al., "Establishment of a Continuous Tumor-Cell Line (PANC-1) from a Human Carcinoma of the Exocrine Pancreas", INT. J. CANCER, 1975, 15:741-747.	
	CK**	NAYA et al., "Diabetes, defective pancreatic morphogenesis, and abnormal enteroendocrine differentiation in BETA2/NeuroD-deficient mice", GENES & DEVELOPMENT, 1997, 11:2323-2334.	
	CL**	OSAKI et al., "Gene Therapy for Carcinoembryonic Antigene-producing Human Lung Cancer Cells by Cell Type-specific Expression of herpes Simplex Virus Thymidine Kinase Gene", CANCER RESEARCH, 1994, 54:5258-5261.	
	CM**	ROBERTSON, et al., "Use of tissue-specific promoter for targeted expression of the herpes simplex virus thymidine kinase gene in cervical carcinoma cells", CANCER GENE THERAPY, Vol. 5, No. 5, 1998, pp. 331-336.	
	CN**	SANDER et al., "The β cell transcription factors and development of the pancreas", J. MOL. MED., 1997, 75(5):327-340 (14 pp).	
	CO**	SCHWARTZ et al., "An orthotopic <i>in vivo</i> model of human pancreatic cancer", SURGERY VOL. 126, No. 3, 1999, pp. 562-567.	
	CP**	SIDERS et al., "Melanoma-specific cytotoxicity induced by a tyrosinase promoter-enhancer/herpes simplex virus thymidine kinase adenovirus", CANCER GENE THERAPY Vol. 5, No. 5, 1998, pp. 181-291.	
	CQ**	TIRONE et al., "Alterations in Insulin Secretion in the Somatostatin Subtype Receptor 5 Knockout Mouse Using the Isolated Perfused Mouse Pancreas Model", SURGICAL FORUM, 86th Annual Clinical Congress 2000, Vol. LI, October 2000, pp. 44-46.	
	CR**	TIRONE et al., "PANC-1 Cells can be Targeted <i>In vitro</i> with a Rat Insulin Promoter Thymidine Kinase Construct", Society for Surgery of the Alimentary Tract, 41st Annual Meeting at Digestive Disease Week, 2794, SSAT/Ross Residents' Conference, San Diego, CA, May 20, 2000 (2 pp).	
	CS**	FAGAN et al., "Insulin secretion is inhibited by subtype five somatostatin receptor in the mouse", SURGERY, Vol. 124, No. 2, 1998, pp. 254-259.	
	CT**	RAY et al., "A Mouse Model for Beta Cell-Specific Ablation of Target Gene(s) using the Cre-loxP System", BIOCHEMICAL AND BIOPHYSICAL RESEARCH COMMUNICATIONS, 1998, 253:65-69.	
	CU**	KLEINMAN et al., "Differential Inhibition of Insulin and islet Amyloid Polypeptide Secretion by Intra-islet Somatostatin in the Isolated Perfused Human Pancreas", PANCREAS, Vol. 19, No. 4, Nov. 1999, pp. 346-352.	
	CV**	ATIYA et al., "Intra-islet Somatostatin Inhibits Insulin (Via a Subtype-2 Somatostatin Receptor) But Not Islet Amyloid Polypeptide Secretion in the Isolated Perfused Human Pancreas", JOURNAL OF GASTROINTESTINAL SURGERY, Vol. 1, No. 3, 1997, pp. 251-256.	
	CW**	MOLDOVAN et al., "Cloning of the Mouse SSTR5 Gene", JOURNAL OF SURGICAL RESEARCH, 1998, 76:57-60.	
Examiner Signature			Date Considered

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Sheet	3	of	4	Attorney Docket Number	60710-00002USC1

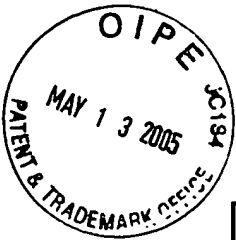
	CX**	REN et al., "Activation of Human Somatostatin Receptor Type 2 Causes Inhibition of Cell Growth in Transfected HEK293 but not in Transfected CHO Cells", JOURNAL OF SURGICAL RESEARCH, 1997, 71:13-18.	
	CY**	KLEINMAN et al., "Regulatory Role of Intraislet Somatostatin on Insulin Secretion in the isolated Perfused Human Pancreas", PANCREAS, Vol. 9, No. 2, pp. 172-178.	
	CZ**	AHLGREN et al., "Beta-cell-specific inactivation of the mouse <i>Ip1/Pdx1</i> gene results in loss of the β -cell phenotype and maturity onset diabetes", GENES & DEVELOPMENT, 1998, 12:1763-1768.	
	CA1**	AL-HENDY et al., "Applying the Herpes Simplex Virus Thymidine Kinase/Ganciclovir Approach to Ovarian Cancer: An Effective <i>in vitro</i> Drug-Sensitization System", GYNECOLOGIC AND OBSTETRIC INVESTIGATION, 1997, 43:268-275.	
	CB1**	BONNEKOH et al., "Inhibition of Melanoma Growth by Adenoviral Mediated HSV Thymidine Kinase Gene Transfer <i>in vivo</i> ", THE JOURNAL OF INVESTIGATIVE DERMATOLOGY, 1995, 104:313-317.	
	CC1**	CHEN et al., "Gene Therapy for brain tumors: Regression of experimental gliomas by adenovirus-mediated gene transfer <i>in vivo</i> ", PROC. NATL. ACAD. SCI. USA, 1994, 91:2054-3057.	
	CD1**	RAY et al., "Development of a Transgenic Mouse Model Using Rat Insulin Promoter to Drive the Expression of CRE Recombinase in a Tissue-Specific Manner", INTERNATIONAL JOURNAL OF PANCREATOLOGY, Vol. 25, No. 3, June 1999, pp. 157-163.	
	CE1**	CROWE et al., "Mutagenesis of the Rat Insulin II 5'-Flanking Region Defines Sequences Important for Expression in HIT Cells", MOLECULAR AND CELLULAR BIOLOGY, Vol. 9, No. 4, April 1989, pp. 1784-1789.	
	CF1**	TIRONE et al., "Beta Cell Specific Cytotoxicity using a Rat Insulin Promoter Thymidine Kinase Construct", Association of Academic Surgery-Abstracts, 33rd Annual Meeting, Philadelphia, PA, Nov. 18-20, 1999, pp. 287-288.	
	CG1**	SMYTH-TEMPLETON et al., "Improved DNA: liposome complexes for increased systemic delivery and gene expression", NATURE BIOTECHNOLOGY, 1997, 15:647-652.	
	CH1**	ST-ONGE et al., "Pancreas development and diabetes", CURRENT OPINION IN GENETICS DEVELOPMENT 1999, 9:295-300.	
	CI1**	STROWSKI et al., "Somatostatin inhibits insulin and Glucagon Secretion via Two Receptor Subtypes: An <i>in vitro</i> Study of Pancreatic Islets from Somatostatin Receptor 2 Knockout Mice", ENDOCRINOLOGY, Vol. 141, No. 1, 2000, pp.111-117.	
	CJ1**	TANAKA et al., "Adenovirus-Mediated Gene Therapy of Gastric Carcinoma Using Cancer-Specific Gene Expression <i>in vivo</i> ", BIOCHEMICAL AND BIOPHYSICAL RESEARCH COMMUNICATIONS, 1997, 231:775-779.	
	CK1**	TONG et al., " <i>In vivo</i> Gene Therapy of Ovarian Cancer by Adenovirus-Mediated Thymidine Kinase Gene Transduction and Ganciclovir Administration", GYNECOLOGIC ONCOLOGY, 1996, 61:175-179.	
	CL1**	VANDIER et al., "Selective Killing of Glioma Cell Lines Using an Astrocyte-specific Expression of the Herpes Simplex Virus-Thymidine Kinase Gene", CANCER RESEARCH, 1998, 58:4577.4580.	
	CM1*	TONG et al., "Adenovirus-Mediated Thymidine Kinase Gene Transduction in Human Epithelial Ovarian Cancer Cell Lines Followed by Exposure to Ganciclovir", ANTICANCER RESEARCH, 1996, 16:1611-1617.	
	CN1**	HALLORAN et al., "Gene Therapy for Pancreatic Cancer - Current and Prospective Strategies, 2000, SURGICAL ONCOLOGY, Vol. 9, Elsevier, pp. 181-191.	
	CO1**	MELLOUL et al., "Regulation of insulin gene transcription", 2002, DIABETOLOGIA, Springer-Verlag, pp. 309-326.	
	CP1**	RAY et al., "Beta Cell-Specific Ablation of Target Gene Using Cre-loxP System in Transgenic Mice", 1999, JOURNAL OF SURGICAL RESEARCH, Vol. 84, pp. 199-203.	
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Sheet	4	of	4	Attorney Docket Number	60710-00002USC1

CQ1**	LEDLEY, "Clinical Considerations in the Design of Protocols for Somatic Gene Therapy", 1991, HUMAN GENE THERAPY 2:77-83.	
CR1**	ECK et al., "Gene-Based Therapy", 1990:77-100.	
CS1**	MILLER et al., "Targeted vectors for gene therapy", 1995, FASEB J., 9:190-199.	
CT1**	DEONARAIN, "Ligand-targeted receptor-mediated vectors for gene delivery", 1998, Ecp. Opin. Ther. Patents 8(1):53-69.	
CU1**	VERMA et al., "Gene therapy-promises, problems and prospects", 1997, NATURE, Vol. 389:239-242.	
CV1**	CRYSTAL, "Transfer of Genes to Humans: Early Lessons and Obstacles to Success", 1995, SCIENCE, Vol. 270:404-410.	
CW1*	ROMANO et al., "Gene Transfer Technology in Therapy: Current Applications and Future Goals", 1999, Stem Cells 17:191-202.	
CX1**	WELSH et al., "Stimulation of pancreatic islet beta-cell replication by oncogenes", 1988, Proc. Natl. Acad. Sci., Vol. 85:116-120.	
CY1**	SELJFFERS et al., "Increase in PDX-1 Levels Suppresses Insulin Gene Expression in RIN 1046-38 Cells", 1999, Endocrinology, Vol. 140:3311-3317.	
CZ1**	TRASK et al., "Phase I Study of Adenoviral Delivery of the HSV-tk Gene and Ganciclovir Administration in Patients with Recurrent Malignant Brain Tumors", MOLECULAR THERAPY, 2000, Vol. 1, No. 2, pp. 195-203.	
CA2**	SUNG et al., "Intratumoral adenovirus-mediated suicide gene transfer for hepatic metastases from colorectal adenocarcinoma: Results of a phase I clinical trial", MOL. THER., 2001, Sep; 4(3):182-191.	
CB2**	O'MALLEY et al., "Adenovirus-mediated gene therapy for human head and neck squamous cell cancer in a nude mouse model", CANCER RES., 1995, March 1: 55(5):1080-1085.	
CC2**	TIRONE et al., "Cell-Specific Cytotoxicity of Human Pancreatic Adenocarcinoma Cells using Rat Insulin Promoter Thymidine Kinase Directed Gene Therapy", Michael E. DeBakey Dept. of Surgery, Dept. of Molecular and Cellular Biology and Center for Cell and Gene Therapy, Baylor College of Medicine, Houston, TX, pp. 2-32.	
CD2**	YAZAWA et al., "Current Progress in Suicide Gene Therapy for Cancer", WORLD JOURNAL OF SURGERY, 26, PP. 783-789, 2002.	
CE2**	KOURAKLIS, "Progress in cancer gene therapy", ACTA ONCOL., 1999:38(6):675-83.	
CF2**	KLATZMANN et al., "A phase I/II study of herpes simplex virus type 1 thymidine kinase "suicide" gene therapy for recurrent glioblastoma. Study Group on Gene Therapy for Glioblastoma", HUM GENE THER., 1998 Nov. 20;9(17):2595-604.	
CG2**	FREYTAG et al., "Phase I study of replication-competent adenovirus-mediated double suicide gene therapy for the treatment of locally recurrent prostate cancer", CANCER RES. 2002 Sep. 1;62(17):4968-76.	
CH2**	SHALEV et al., "Suicide gene therapy for prostate cancer using a replication-deficient adenovirus containing the herpesvirus thymidine kinase gene", WORLD J UROL. 2000 18:125-129.	
CA3	WANG et al., "Specific Gene Expression and Therapy for Pancreatic Cancer Using the Cytosine Deaminase Gene Directed by the Rat Insulin Promoter", J of GASTROINTESTINAL SURGERY, 2004, Vol. 8 No. 1:98-108.	
CB3	TIRONE et al., "Insulinoma-Induced Hypoglycemic Death in Mice is Prevented with Beta Cell-Specific Gene Therapy", ANNALS OF SURGERY, Vol. 233, No. 5, May 2001:603-611	
CC3	TIRONE et al., "Cell-specific Cytotoxicity of Human Pancreatic Adenocarcinoma Cells Using Rat Insulin Promoter Thymidine Kinase-directed Gene Therapy", WORLD J. OF SURGERY, 2004, 28, 826-833.	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. **CITE NO.: Those patent(s) or publication(s) which are marked with an double

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Application No. (if known): 10/656450

Attorney Docket No.: 60710-00002USC1

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